Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2132652	03/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Xytex Laboratories, Inc	303 George Street, Suite G-30, New Brunswick, NJ	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the General Supervisor (GS) the laboratory failed to maintain work records for two of two PT events with the American Associations of Bioanalysts (AAB) in the calendar year 2017. The GS confirmed on 3/27/18 at 11:00 am that PT records were not maintained.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS) the laboratory failed to have a procedure for Verification of Quality Control Material (VQCM) from 11/2/16 to the date of the survey. The GS confirmed on 3/27/18 at 10:30 am that the laboratory failed to have a procedure for VQCM.
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the General Supervisor (GS) the laboratory failed to ensure that the Reference Interval (RI) were reported for Semen Analysis from 8/3/17 to the date of survey. The finding includes: 1. A review of three out of seven FR revealed that RI were reported only for abnormal results. 2. The GS confirmed on 3/27/18 at 11:30 am that the laboratory did not report correct RI on the FR.